



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Walter Callen et al. Art Unit: 1631

Serial No.: 10/034,621 Examiner: Richard Hutson, Ph.D.

Filed: December 21, 2001

Title : ENZYMES HAVING HIGH TEMPERATURE POLYMERASE ACTIVITY AND

METHODS OF USE THEREOF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

- 1. I, Jay M. Short, am an expert in the field of molecular biology and enzyme development and was an expert at the time of the invention. I am presently employed as a CEO and as a research scientist at Diversa Corporation, San Diego, CA, assignee of the above-referenced patent application. My resume is attached as documentation of my credentials.
- 2. I declare that the the state of the art at the time of the invention and the level of skill of the person of ordinary skill in the art, e.g., screening enzymes, and nucleic acids encoding enzymes, for various polymerase activities, e.g., thermostable DNA polymerase activity, was very high. Using the teaching of the specification, one skilled in the art could have selected routine methods known in the art at the time of the invention to express variants of nucleic acids encoding the exemplary enzyme of the invention and screen them for expression of polypeptides having various polymerase activities. One skilled in the art could have used routine protocols known in the art at the time of the invention, including those described in the instant specification, to screen for nucleic acids encoding polypeptides having a percent sequence

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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identity to SEQ ID NO:1, or active fragments thereof, for various polymerase activities. At the time of the invention it was routine to screen for multiple substitutions or multiple modifications of an enzyme-encoding sequence and predictably achieve positive results. While the numbers of samples needed to be screened may have been high, the screening procedures were routine and successful results (i.e., finding variant nucleic acids encoding polymerases having various activities) predictable. Furthermore, it would not have required any knowledge or guidance as to which are the specific structural elements, e.g., amino acid residues, that correlate with polymerase activity to create variants of the exemplary nucleic acid and test them for the expression of polypeptides or peptides having polymerase activity. Accordingly, it would not have taken undue experimentation to make and use the claimed invention, including identification of a genus of nucleic acids encoding polymerases active under various conditions.

Attorney's Docket No.: 09010-027007 / DIVER 1350-6

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted

Date:

Jaly M. Short